

to a defined testing period before the broader distribution of that substitute in interstate commerce.

*Use* means any use of a substitute for a Class I or Class II ozone-depleting compound, including but not limited to use in a manufacturing process or product, in consumption by the end-user, or in intermediate uses, such as formulation or packaging for other subsequent uses.

*Use restrictions* means restrictions on the use of a substitute imposing either conditions on how the substitute can be used across a sector end-use or limits on the end-uses or specific applications where it can be used within a sector.

#### § 82.174 Prohibitions.

(a) No person may introduce a new substitute into interstate commerce before the expiration of 90 days after a notice is initially submitted to EPA under § 82.176(a).

(b) No person may use a substitute which a person knows or has reason to know was manufactured, processed or imported in violation of the regulations in this subpart, or knows or has reason to know was manufactured, processed or imported in violation of any use restriction in the acceptability determination, after the effective date of any rulemaking imposing such restrictions.

(c) No person may use a substitute without adhering to any use restrictions set by the acceptability decision, after the effective date of any rulemaking imposing such restrictions.

(d) No person may use a substitute after the effective date of any rulemaking adding such substitute to the list of unacceptable substitutes.

(e) *Rules Stayed for Reconsideration.* Notwithstanding any other provision of this subpart, the effectiveness of subpart G is stayed from December 8, 1994, to March 8, 1995, only as applied to use of substitutes for export.

[59 FR 13147, Mar. 18, 1994, as amended at 59 FR 63256, Dec. 8, 1994; 60 FR 3303, Jan. 13, 1995]

#### § 82.176 Applicability.

(a) Any producer of a new substitute must submit a notice of intent to introduce a substitute into interstate

commerce 90 days prior to such introduction. Any producer of an existing substitute already in interstate commerce must submit a notice as of July 18, 1994, if such substitute has not already been reviewed and approved by the Agency.

(b) With respect to the following substitutes, producers are exempt from notification requirements:

(1) *Substitutes already listed as acceptable.* Producers need not submit notices on substitutes that are already listed as acceptable under SNAP.

(2) *Small sectors.* Persons using substitutes in sectors other than the nine principal sectors reviewed under this program are exempt from the notification requirements. This exemption shall not be construed to nullify an unacceptability determination or to allow use of an otherwise unacceptable substitute.

(3) *Small volume use within SNAP sectors.* Within the nine principal SNAP sectors, persons introducing a substitute whose expected volume of use amounts to less than 10,000 lbs. per year within a SNAP sector are exempt from notification requirements. This exemption shall not be construed to allow use of an otherwise unacceptable substitute in any quantity. Persons taking advantage of this exemption for small uses must maintain documentation for each substitute describing how the substitute meets this small use definition. This documentation must include annual production and sales information by sector.

(4) *Research and development.* Production of substitutes for the sole purpose of research and development is exempt from reporting requirements.

(5) *Test marketing.* Use of substitutes for the sole purpose of test marketing is exempt from SNAP notification requirements until 90 days prior to the introduction of such substitutes for full-scale commercial sale in interstate commerce. Persons taking advantage of this exemption are, however, required to notify the Agency in writing that they are conducting test marketing 30 days prior to the commencement of such marketing. Notification shall include the name of the substitute, the volume used in the test marketing, intended sector end-uses,

and expected duration of the test marketing period.

(6) *Formulation changes.* In cases where replacement of class I or II compounds causes formulators to change other components in a product, formulators are exempt from reporting with respect to these auxiliary formulation changes. However, the SNAP submitter is required to notify the Agency if such changes are expected to significantly increase the environmental and human health risk associated with the use of any class I or class II substitute.

(7) *Substitutes used as feedstocks.* Producers of substitutes used as feedstocks which are largely or entirely consumed, transformed or destroyed in the manufacturing or use process are exempt from reporting requirements concerning such substitutes.

(c) Use of a substitute in the possession of an end-user as of March 18, 1994, listed as unacceptable or acceptable subject to narrowed use limits may continue until the individual end-users' existing supply, as of that date, of the substitute is exhausted. Use of substitutes purchased after March 18, 1994, is not permitted subsequent to April 18, 1994.

**§ 82.178 Information required to be submitted.**

(a) Persons whose substitutes are subject to reporting requirements pursuant to § 82.176 must provide the following information:

(1) *Name and description of the substitute.* The substitute should be identified by its: Chemical name; trade name(s); identification numbers; chemical formula; and chemical structure.

(2) *Physical and chemical information.* The substitute should be characterized by its key properties including but not limited to: Molecular weight; physical state; melting point; boiling point; density; taste and/or odor threshold; solubility; partition coefficients (Log  $K_{ow}$ , Log  $K_{oc}$ ); atmospheric lifetime and vapor pressure.

(3) *Substitute applications.* Identification of the applications within each sector end-use in which the substitutes are likely to be used.

(4) *Process description.* For each application identified, descriptive data on

processing, including in-place pollution controls.

(5) *Ozone depletion potential.* The predicted 100-year ozone depletion potential (ODP) of substitute chemicals. The submitter must also provide supporting documentation or references.

(6) *Global warming impacts.* Data on the total global warming potential of the substitute, including information on the GWP index and the indirect contributions to global warming caused by the production or use of the substitute (e.g., changes in energy efficiency). GWP must be calculated over a 100, 500 and 1000-year integrated time horizon.

(7) *Toxicity data.* Health and safety studies on the effects of a substitute, its components, its impurities, and its degradation products on any organism (e.g., humans, mammals, fish, wildlife, and plants). For tests on mammals, the Agency requires a minimum submission of the following tests to characterize substitute risks: A range-finding study that considers the appropriate exposure pathway for the specific use (e.g., oral ingestion, inhalation, etc.), and a 90-day subchronic repeated dose study in an appropriate rodent species. For certain substitutes, a cardiotoxicity study is also required. Additional mammalian toxicity tests may be identified based on the substitute and application in question. To sufficiently characterize aquatic toxicity concerns, both acute and chronic toxicity data for a variety of species are required. For this purpose, the Agency requires a minimum data set as described in "Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and their Uses," which is available through the National Technical Information Service (#PB 85-227049). Other relevant information and data summaries, such as the Material Safety Data Sheets (MSDS), should also be submitted. To assist in locating any studies previously submitted to EPA and referred to, but not included in a SNAP submission, the submitter must provide citations for the date, type of submission, and EPA Office to which they were submitted, to help EPA locate these quickly.

(8) *Environmental fate and transport.* Where available, information must be